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TO: Director, Center for Devices and Radiological Health
Dockets Management Branch
(HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

FROM: Electronic Service Agency, Kenneth Pfaff

Source of Device:
Applied Imaging Group **(AIG)**, England
55 Park View
Great Stukeley
Huntingdon, CAMBS PE17 5AJ
England, United Kingdom

US Agent / Reseller:
Electronic Services Agency
15741 US 36 East, 222
Marysville, Ohio 43040-9484
937-644-2170
937-644-8382 FAX

DATE: 27 June 2000

SUBJECT: Variance / Exemption
DEVICE: AIG Limelight 200 and 45 Class IIIB Laser Diode Infrared Illuminators

DETAILS
Electronic Services Agency (ESA) in Ohio is asking for a variance / accession number that would allow ESA to import Class IIIB lasers for police and military applications without modification of the existing product offered by Applied Imaging Group, England, UK. The Applied Imaging Group has two models of laser diode infrared illuminators. The devices are the Limelight 200 and 45. The illuminators are hand held, battery operated, employing Class IIIB laser diodes operating at 812 nanometers / 117 milliwatts for the LL200 and 820 nanometers / 37 milliwatts for the LL45.

The Limelight 200 and 45 were designed by Roy Thompson, formerly of the Police Scientific Development Branch, Home Office, England. The principal application is for police and military operations in United Kingdom where a small infrared illuminator was required for short duration covert night operations.

The standard infrared illuminator uses an incandescent lamp behind an infrared filter. These standard units are very inefficient as only a small percentage of the energy is emitted as non-visible light. The rest of the energy is converted to heat. The standard low efficiency illuminators are ideal for long term operations where power can be provided by large batteries or AC power and a fully covert infrared light source is required. The Limelight is ideal for short duration portable use due to the Limelights shirt pocket size.

The Limelight operates at the edge of visible light. This causes the diode to glow red and is visible to the naked eye at the source. A few feet from the lens, the beam is invisible. The advantage of this wavelength is that the light is close enough to the visible range at which most black and white CCD cameras can still focus correctly. As the wavelength moves further away from the visible range, the

black and white cameras have greater difficulty with focus. Consequently, the video image begins to look blurred.

The Limelights are designed to work with night vision equipment and thus would not be used in daylight. This factor helps in the safe operation of the units. A typical use would be in a poorly

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AIG Limelight 200 and 45 Class IIIB Laser Diode Infrared Illuminators (Continued)

illuminated area where night vision equipment requires additional illumination to see the subjects or area. When operated properly, the Limelight bears the same properties as a Class 1 laser.

The Limelight would be an ideal tool for military and police applications and would provide a competitor in this market that is largely held by B.E. Meyers. Sales would be restricted to law enforcement and military.

1010.4.b

(i) Description of Product and its intended use
The Limelight 200/45 is a hand held infrared illuminator that uses a laser diode. The unit measures about 7.5 inches in length and 1.25 inches in diameter. The product is available with 117mW 812 nm or 37mW 820 nm laser. The intended use is for military and law enforcement to use with night vision equipment for observation of subjects or areas from a distance. The diode has a visible red glow at the source and thus is not ideal for short distances. The source is overt and can be see with the naked eye.

(ii) Compliance restrictive or inappropriate
The Limelight is intended for covert night operations. Compliance would require adding audible and visible alarms when the laser in on. These features would not be ideal for covert night applications and could endanger the user from hostile weapons assaults.

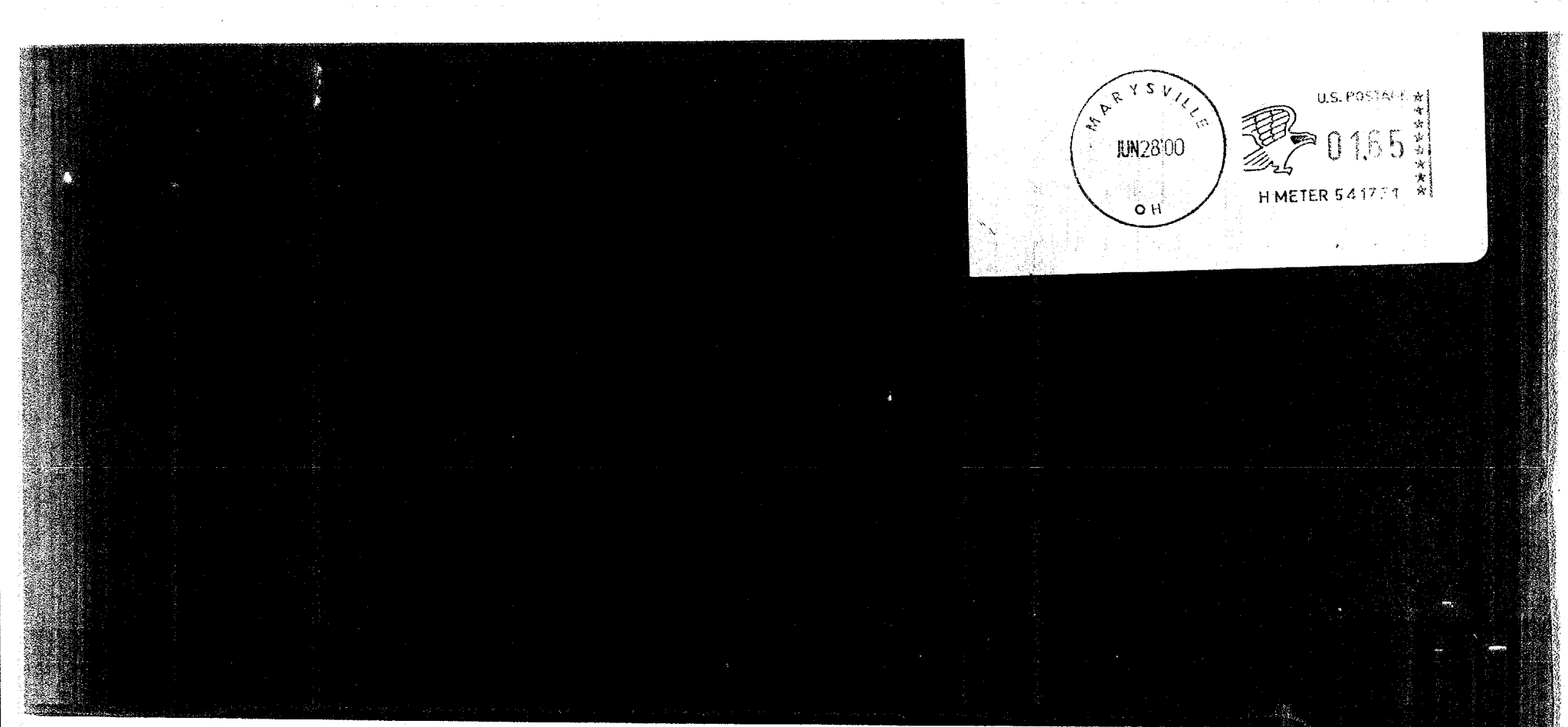
(iii) Deviation from standards
The Limelight will have no visible or audible alarms during operation.

(iv) Advantages from deviation
The Limelight can be deployed without putting the operator in danger from hostile weapons fire.

(v) Alternate Radiation protection.
With proper instruction, the Limelight can be used safely. Typical application requires the user to use night vision equipment, which will make the infrared beam visible. In typical stored position, the lens at its widest angle creates a beam that is eye safe at very short distances and the source is visible to the naked eye. Typical operational use of these illuminators is measured in tens of yards, which makes the radiation safe to the user and subject.

(vii) Prototype
N/A

(viii) Other Information
The Limelight products are similar to products sold by B.E. Meyers for the same application. See attached printout from B.E. Meyers web site.



Electronic Services Agency

East Pointe Plaza, 15741 U.S. 36 East, Unit 222
Marysville, OH 43040 USA

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